Memorandum of Meeting Minutes

Meeting Date:	October 28, 1998
Time:	12:00 p.m. to 1:30 p.m.
Location:	9201 Corporate Boulevard, Rooms S200A & B
Type of Meeting:	Public Feedback Meeting
Topic:	Sunscreen Monograph/Foreign Marketing Proposal
Chairperson:	Donald Dobbs
Project Manager:	Babette Merritt

FDA Participants:

Robert DeLap, M.D., Director ODE-V, HFD-105
Debra Bowen, M.D., Deputy Director, ODE-V, HFD-105
Steven Aurecchia, M.D., Medical Officer, DOTCDP, HFD-560
Kay Freeman, Microbiologist, DOTCDP, HFD-560
Gerald M. Rachanow, Regulatory Counsel, DOTCDP, HFD-560
Donald Dobbs, Interdisciplinary Scientist, DOTCDP, HFD-560
John Lipnicki, Team Leader, DOTCDP, HFD-560
Jane Axelrad, Associate Director for Policy, OD, HFD-005

European Sunscreen Manufacturers Coalition participants:

Eve Bachrach, Senior Vice President, General Counsel, NDMA
Kathy Sanzo, Esquire, Morgan, Lewis & Bockius
Ina Hofgen-Muller, Regulatory Affairs Manager, Merck in Germany
Rolf-Dieter Reinhardt, Regulatory Affairs Manager, BASF AG, Germany
Robert Pinco, Esquire, Akin Gump
Mary Johnson, Esquire, Akin Gump
Doug Manning, Rona/Merck
Karl A. Hann, H & R Florasynth, TA Business, VMIT Manager

Objective: To discuss agenda items submitted by the European Sunscreen Manufacturers Coalition (ESMC).

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Discussion Points:

1. Mr. Pinco presented the following issues on behalf of the ESMC:

- An introduction indicating that they are bulk suppliers of sunscreen active ingredients and that their products are sold world-wide but not in the United States.

- Pending sunscreen petitions with FDA:

    a. Merck, 1984
    b. BASF, AG, 1989
    c. Haarmann and Reimer, 1990
    d. BASF, AG, 1996

- Discussion of points related to the Foreign Marketing Proposal:

    a. Six years ago the Agency was petitioned to open the OTC review to foreign ingredients.
    b. FDA issued an Advanced Notice of Proposed Rule two years ago.
    c. Need feedback from FDA.
    d. Dialogue is supposed to be part of the rule-making process.
    e. Suggestion to look at foreign OTC marketing and foreign sunscreen regulatory documents.
    f. There have been many changes in foreign marketing overseas.
    g. Need to publish the sunscreen monograph per FDAMA.
    h. United States is 40 percent of the world market for sunscreens
    i. ESMC has new sunscreen active ingredients it wants to develop, but has no incentive to develop these ingredients without access to U.S. market through the OTC drug monograph system.
    j. The NDA system does not work for foreign sunscreen ingredients. There is a need to get these ingredients into the monograph so one can reformulate and be competitive with existing monographed sunscreen ingredients marketed in the U.S.
    k. Consumers have a need for prompt access to these products (see handout).
    l. Need to review the outstanding petitions covering four ingredients.
    m. Suggest hiring outside experts to facilitate the review process (see handout).
    n. Questions to the agency:

        1. Where is the Foreign Marketing Proposal and when will it publish?
        2. What is delaying this?
        3. What is the time frame?
        4. What are the Agency's criteria?

2. Agency representatives made the following comments:

- These products were not previously marketed in the US. The foreign marketing proposal will address these and other OTC products in different therapeutic areas. There is a need to consider an overall structure and we are trying to develop the most efficient process. If Congress intended for the Agency to get out the foreign marketing proposed rule by May 1999, we will try to meet the Congressional date.

- The Agency is concerned about the public health issue related to sunscreens. Both product safety and effectiveness are concerns. This is a priority issue and we are definitely working on getting both the sunscreen and foreign marketing documents completed. We really cannot say any more about these pending rulemakings at this time.

- FDAMA has intervened and other monograph issues were put on the priority list. However, we are still actively working on completing the foreign marketing proposed rule.

3. ESMC representatives replied:

- They disagree that we cannot have dialog while rulemakings are in process. They need feedback and there is frustration for this taking so long.

- They will help at higher levels to get this through the Agency. Companies may be willing to pay for experts to help get the review of sunscreen ingredients done.

Conclusion:

Agency representatives stated that some of the ESMC proposals were interesting and that it would look into them. The Agency will consider the proposal for third party review but reviewers are not the problem. Resources are an issue for the Agency. Also, there are a number of complex issues associated with topical sunscreen preparations.

Babette Merritt, Minutes Preparer

Donald Dobbs, Chair Concurrence

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 12/17/99

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0038

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[ ] This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment